to March 8, 1995, only as applied to use of substitutes for export.

[59 FR 13147, Mar. 18, 1994, as amended at 59 FR 63256, Dec. 8, 1994; 60 FR 3303, Jan. 13, 1995]

§ 82.176 Applicability.

(a) Any producer of a new substitute must submit a notice of intent to introduce a substitute into interstate commerce 90 days prior to such introduction. Any producer of an existing substitute already in interstate commerce must submit a notice as of July 18, 1994, if such substitute has not already been reviewed and approved by the Agency.

(b) With respect to the following substitutes, producers are exempt from notification requirements:

(1) *Substitutes already listed as acceptable.* Producers need not submit notices on substitutes that are already listed as acceptable under SNAP.

(2) *Small sectors.* Persons using substitutes in sectors other than the nine principal sectors reviewed under this program are exempt from the notification requirements. This exemption shall not be construed to nullify an unacceptability determination or to allow use of an otherwise unacceptable substitute.

(3) *Small volume use within SNAP sectors.* Within the nine principal SNAP sectors, persons introducing a substitute whose expected volume of use amounts to less than 10,000 lbs. per year within a SNAP sector are exempt from notification requirements. This exemption shall not be construed to allow use of an otherwise unacceptable substitute in any quantity. Persons taking advantage of this exemption for small uses must maintain documentation for each substitute describing how the substitute meets this small use definition. This documentation must include annual production and sales information by sector.

(4) *Research and development.* Production of substitutes for the sole purpose of research and development is exempt from reporting requirements.

(5) *Test marketing.* Use of substitutes for the sole purpose of test marketing is exempt from SNAP notification requirements until 90 days prior to the introduction of such substitutes for full-scale commercial sale in interstate commerce. Persons taking advantage of this exemption are, however, required to notify the Agency in writing that they are conducting test marketing 30 days prior to the commencement of such marketing. Notification shall include the name of the substitute, the volume used in the test marketing, intended sector end-uses, and expected duration of the test marketing period.

(6) *Formulation changes.* In cases where replacement of class I or II compounds causes formulators to change other components in a product, formulators are exempt from reporting with respect to these auxiliary formulation changes. However, the SNAP submitter is required to notify the Agency if such changes are expected to significantly increase the environmental and human health risk associated with the use of any class I or class II substitute.

(7) *Substitutes used as feedstocks.* Producers of substitutes used as feedstocks which are largely or entirely consumed, transformed or destroyed in the manufacturing or use process are exempt from reporting requirements concerning such substitutes.

(c) Use of a substitute in the possession of an end-user as of March 18, 1994, listed as unacceptable or acceptable subject to narrowed use limits may continue until the individual end-users' existing supply, as of that date, of the substitute is exhausted. Use of substitutes purchased after March 18, 1994, is not permitted subsequent to April 18, 1994.

§ 82.178 Information required to be submitted.

(a) Persons whose substitutes are subject to reporting requirements pursuant to § 82.176 must provide the following information:

(1) *Name and description of the substitute.* The substitute should be identified by its: Chemical name; trade name(s); identification numbers; chemical formula; and chemical structure.

(2) *Physical and chemical information.* The substitute should be characterized by its key properties including but not limited to: Molecular weight; physical

state; melting point; boiling point; density; taste and/or odor threshold; solubility; partition coefficients (Log K_{ow}, Log K_{oc}); atmospheric lifetime and vapor pressure.

(3) *Substitute applications.* Identification of the applications within each sector end-use in which the substitutes are likely to be used.

(4) *Process description.* For each application identified, descriptive data on processing, including in-place pollution controls.

(5) *Ozone depletion potential.* The predicted 100-year ozone depletion potential (ODP) of substitute chemicals. The submitter must also provide supporting documentation or references.

(6) *Global warming impacts.* Data on the total global warming potential of the substitute, including information on the GWP index and the indirect contributions to global warming caused by the production or use of the substitute (e.g., changes in energy efficiency). GWP must be calculated over a 100, 500 and 1000-year integrated time horizon.

(7) *Toxicity data.* Health and safety studies on the effects of a substitute, its components, its impurities, and its degradation products on any organism (e.g., humans, mammals, fish, wildlife, and plants). For tests on mammals, the Agency requires a minimum submission of the following tests to characterize substitute risks: A range-finding study that considers the appropriate exposure pathway for the specific use (e.g., oral ingestion, inhalation, etc.), and a 90-day subchronic repeated dose study in an appropriate rodent species. For certain substitutes, a cardiotoxicity study is also required. Additional mammalian toxicity tests may be identified based on the substitute and application in question. To sufficiently characterize aquatic toxicity concerns, both acute and chronic toxicity data for a variety of species are required. For this purpose, the Agency requires a minimum data set as described in "Guidelines for Deriving Numerical National Water Quality Criteria for the Protection of Aquatic Organisms and their Uses," which is available through the National Technical Information Service (#PB 85–227049). Other relevant information and data summaries, such as the Material Safety Data Sheets (MSDS), should also be submitted. To assist in locating any studies previously submitted to EPA and referred to, but not included in a SNAP submission, the submitter must provide citations for the date, type of submission, and EPA Office to which they were submitted, to help EPA locate these quickly.

(8) *Environmental fate and transport.* Where available, information must be submitted on the environmental fate and transport of substitutes. Such data shall include information on bioaccumulation, biodegradation, adsorption, volatility, transformation, and other data necessary to characterize movement and reaction of substitutes in the environment.

(9) *Flammability.* Data on the flammability of a substitute chemical or mixture are required. Specifically, the flash point and flammability limits are needed, as well as information on the procedures used for determining the flammability limits. Testing of blends should identify the compositions for which the blend itself is flammable and include fractionation data on changes in the composition of the blend during various leak scenarios. For substitutes that will be used in consumer applications, documentation of testing results conducted by independent laboratories should be submitted, where available. If a substitute is flammable, the submitter must analyze the risk of fire resulting from the use of such a substitute and assess the effectiveness of measures to minimize such risk.

(10) *Exposure data.* Available modeling or monitoring data on exposures associated with the manufacture, formulation, transport, use and disposal of a substitute. Descriptive process information for each substitute application, as described above, will be used to develop exposure estimates where exposure data are not readily available. Depending on the application, exposure profiles may be needed for workers, consumers, and the general population.

(11) *Environmental release data.* Data on emissions from the substitute application and equipment, as well as on pollutant releases or discharge to all environmental media. Submitters should provide information on release locations, and data on the quantities,

including volume, of anticipated waste associated with the use of the substitute. In addition, information on anticipated waste management practices associated with the use of the substitute. Any available information on any pollution controls used or that could be used in association with the substitute (e.g., emissions reduction technologies, wastewater treatment, treatment of hazardous waste) and the costs of such technology must also be submitted.

(12) *Replacement ratio for a chemical substitute.* Information on the replacement ratio for a chemical substitute versus the class I or II substances being replaced. The term "replacement ratio" means how much of a substitute must be used to replace a given quantity of the class I or II substance being replaced.

(13) *Required changes in use technology*. Detail on the changes in technology needed to use the alternative. Such information should include a description of whether the substitute can be used in existing equipment—with or without some retrofit—or only in new equipment. Data on the cost (capital and operating expenditures) and estimated life of any technology modifications should also be submitted.

(14) *Cost of substitute.* Data on the expected average cost of the alternative. In addition, information is needed on the expected equipment lifetime for an alternative technology. Other critical cost considerations should be identified, as appropriate.

(15) *Availability of substitute.* If the substitute is not currently available, the timing of availability of a substitute should be provided.

(16) *Anticipated market share.* Data on the anticipated near-term and long-term nationwide substitute sales.

(17) *Applicable regulations under other environmental statutes.* Information on whether the substitute is regulated under other statutory authorities, in particular the Clean Water Act, Safe Drinking Water Act, the Resource Conservation and Recovery Act, the Federal Insecticide, Fungicide, and Rodenticide Act, the Toxic Substances Control Act, the Comprehensive Environmental Response, Compensation and Liability Act, the Emergency Planning and Community Right-to-Know Act, or other titles under the Clean Air Act.

(18) *Information already submitted to the Agency*. Information requested in the SNAP program notice that has been previously submitted to the Agency as part of past regulatory and information-gathering activities may be referenced rather than resubmitted. Submitters who cannot provide accurate references to data sent previously to the Agency should include all requested information in the SNAP notice.

(19) *Information already available in the literature.* If any of the data needed to complete the SNAP program notice are available in the public literature, complete references for such information should be provided.

(b) The Significant New Alternatives Policy (SNAP) Information Notice is designed to provide the Agency with the information necessary to reach a decision on the acceptability of a substitute.

(1) Submitters requesting review under the SNAP program should send the completed SNAP notice to: SNAP Document Control Officer, U.S. Environmental Protection Agency (6205–J), 401 M Street, SW., Washington, DC 20460.

(2) Submitters filing jointly under SNAP and the Premanufacture Notice Program (PMN) should send the SNAP addendum along with the PMN form to: PMN Document Control Officer, U.S. Environmental Protection Agency (7407), 401 M Street, SW., Washington, DC 20460. Submitters must also send both documents to the SNAP program, with a reference to indicate the notice has been furnished to the Agency under the PMN program. Submitters providing information on new chemicals for joint review under the TSCA and SNAP programs may be required to supply additional toxicity data under TSCA section 5.

(3) Submitters filing jointly under SNAP and under the Federal Insecticide, Fungicide, and Rodenticide Act should send the SNAP form to the Office of Pesticide Programs, Registration Division, (7505C) 401 M Street, SW., Washington, DC 20460, as well as

to the SNAP Document Control Officer.

§ 82.180 Agency review of SNAP submissions.

(a) *Processing of SNAP notices.* (1) *90–day review process.* The 90-day review process will begin once EPA receives a submission and determines that such submission includes data on the substitute that are complete and adequate, as described in §82.178. The Agency may suspend or extend the review period to allow for submission of additional data needed to complete the review of the notice.

(2) *Initial review of notice.* The SNAP Document Control Officer will review the notice to ensure that basic information necessary to process the submission is present (i.e., name of company, identification of substitute, etc.). The SNAP Document Control Officer will also review substantiation of any claim of confidentiality.

(3) *Determination of data adequacy.* Upon receipt of the SNAP submission, the Agency will review the completeness of the information supporting the application. If additional data are needed, the submitter will be contacted following completion of this review. The 90-day review period will not commence until EPA has received data it judges adequate to support analysis of the submission.

(4) *Letter of receipt.* The SNAP Document Control Officer will send a letter of receipt to the submitter to confirm the date of notification and the beginning of EPA's 90-day review period. The SNAP Document Control Officer will also assign the SNAP notice a tracking number, which will be identified in the letter of receipt.

(5) *Availability of new information during review period.* If critical new information becomes available during the review period that may influence the Agency's evaluation of a substitute, the submitter must notify the Agency about the existence of such information within 10 days of learning of such data. The submitter must also inform the Agency of new studies underway, even if the results will not be available within the 90-day review period. The Agency may contact the submitter to explore extending or suspending the review period depending on the type of information received and the stage of review.

(6) *Completion of detailed review.* Once the initial data review, described in paragraphs (a)(2) and (3) of this section, has been completed, the Agency will complete a detailed evaluation of the notice. If during any time the Agency perceives a lack of information necessary to reach a SNAP determination, it will contact the submitter and request the missing data.

(7) *Criteria for review.* To determine whether a substitute is acceptable or unacceptable as a replacement for class I or II compounds, the Agency will evaluate:

(i) Atmospheric effects and related health and environmental impacts;

(ii) General population risks from ambient exposure to compounds with direct toxicity and to increased ground-level ozone;

(iii) Ecosystem risks;

(iv) Occupational risks;

(v) Consumer risks;

(vi) Flammability; and

(vii) Cost and availability of the substitute.

(8) *Communication of decision.* (i) *Communication of decision to the submitter.* Once the SNAP program review has been completed, the Agency will notify the submitter in writing of the decision. Sale or manufacture of new substitutes may commence after the initial 90-day notification period expires even if the Agency fails to reach a decision within the 90-day review period or fails to communicate that decision or the need for additional data to the submitter. Sale or manufacture of existing substitutes may continue throughout the Agency's 90-day review.

(ii) *Communication of decision to the public.* The Agency will publish in the FEDERAL REGISTER periodic updates to the list of the acceptable and unacceptable alternatives that have been reviewed to date. In the case of substitutes proposed as acceptable with use restrictions, proposed as unacceptable or proposed for removal from either list, a rulemaking process will ensue. Upon completion of such rulemaking, EPA will publish revised lists of substitutes acceptable subject to use conditions or narrowed use limits and